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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/838,998	04/20/2001	Philip A. Gale	045404.0002	3407

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AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.  
300 WEST 6TH STREET  
SUITE 2100  
AUSTIN, TX 78701

EXAMINER

ANDERSON, REBECCA L

ART UNIT PAPER NUMBER

1626

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/838,998

Applicant(s)

GALE ET AL.

Examiner

Rebecca L. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 120-124 and 127-130 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 120-124 and 127-130 is/are rejected.
- 7) ☒ Claim(s) 120-124 and 127-130 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 120-124 and 127-130 are currently pending in the instant application.

Claims 120-124 and 127-130 are objected and rejected.

#### ***Response to Amendment and Arguments***

Applicants' amendment and arguments filed 9 June 2005 have been entered into the application. While applicant states that the claims have been amended to delete the non-elected subject matter, it is noted that Applicants' amendment to claims 120-124 and 127 did not delete all of the non-elected subject matter as claims 120, 122 and 127-130 contain non-elected subject matter as they are not drawn to the structure I and claims 120-124 contain non-elected subject matter as they are noncovalently-complexed to other than a halide anion. Therefore, the objection to claims 120-124 and 127-130 is maintained.

Applicant's arguments filed 9 June 2005 in regards to the 35 USC 112 1<sup>st</sup> paragraph rejection have been fully considered but they are not persuasive. Applicant traverses this rejection stating that several different types of compositions are described in the specification. Applicant directs the examiners attention to paragraph [0021], however, this paragraph, which teaches uses for the calyx[n]pyrroles, does not teach how to prepare compositions, i.e. what elements or ingredients are combined and how the elements or ingredients are combined and applied to the use. While applicant directs the examiners attention to the electrochemical detection of an anion, cation, or neutral molecule and the removal of pertechnate from nuclear waste, it is again noted that the specification does not teach how to mix or combine various elements or

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ingredients to prepare compositions for these uses and does not direct one of ordinary skill in the art as to what elements or ingredients are combined or how they are combined with the calixpyrrole macrocycle to prepare various compositions besides pharmaceutical compositions and compositions of calyx[n]pyrroles attached to solid supports.

While paragraphs [0024], [0049], [0195], [0196] and example 10 describe calyx[n]pyrroles attached to solid supports for selective separation of a variety of molecules, and describes the supports are, such as silica gels, polymer beads, clays and zeolites, it is noted that the claims are not limited to pharmaceutical compositions and compositions of calyx[n]pyrroles attached to solid supports supported in the specification, but is drawn to compositions, which is a broad category, that does not find support in applicants' instant specification as compositions can include, for example, agricultural compositions such as acaricidal compositions, fungicidal compositions, herbicidal compositions, etc. which applicant does not provide any teaching or direction as to how to prepare these compositions, i.e. what elements or ingredients are combined and how the elements or ingredients are combined and applied to a specific use.

Therefore, the 35 USC 112 1<sup>st</sup> paragraph rejection is maintained as the claims while being enabling for pharmaceutical compositions of the elected invention identified above in the section entitled: The elected invention for search and examination and being enabling for compositions of the calixpyrrole macrocycle with solid supports found in the specification does not reasonably provide enablement for any composition.

***Maintained Claim Objections***

Claims 120-124 and 127-130 are objected to as containing non-elected subject matter. Claims 120-124 and 127-130 presented free of the following 35 USC 112 1<sup>st</sup> paragraph rejection and drawn solely to the elected invention identified on page 3 of the previous office action and reproduced below would appear allowable over the prior art of record.

**The elected invention for search and examination is:** A composition comprising a calix[n]pyrrole macrocycle having the structure I (as seen in claim 121): wherein n is 4, p=q=r=s=0, R1-R16 are independently substituents as listed in i) below, and RA-RD are independently substituents as listed in ii) below;

i) hydrogen, halide, hydroxyl, alkyl, alkenyl or alkynyl;

ii) hydrogen or alkyl;

the macrocycle noncovalently-complexed to a halide anion.

***Maintained Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 120-124 and 127-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pharmaceutical compositions of the elected invention identified above in the section entitled: The elected invention for search and examination and being enabling for compositions of the calixpyrrole macrocycle with solid supports found in the specification does not reasonably provide

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enablement for any composition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case, claims 120-124 and 127-130 are claiming compositions of the elected invention as identified above in the section entitled: The elected invention for search and examination. The state of the prior art is that a composition is a product of mixing or combining various elements or ingredients. While the level of the skill in the art is high, the lack of predictability in the art is that without guidance or direction as to what type of composition is being prepared, one of ordinary skill in the art would not know what elements or ingredients to combine or how to combine with the calix[4]pyrrole macrocycle noncovalently-complexed to a halide anion in order to

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prepare the composition. It would require undue experimentation to prepare compositions other than pharmaceutical compositions and compositions with solid supports, which are the only compositions that are provided support in the instant specification, since there is no direction or guidance present as to what types of compositions can be prepared and how these compositions can be prepared except for pharmaceutical compositions and compositions with solid supports. While compositions can includes such agricultural compositions as acaricidal, herbicidal and insecticidal compositions, there is not direction in the instant specification as to how to prepare or administer these types of compositions. The only examples of compositions in applicants' instant specification is pharmaceutical compositions, see pages 40-42 and example 10 which provides enablement only for pharmaceutical compositions by providing pharmaceutical acceptable carriers, modes of administration, and the treatment of body tissues and which provides enablement only for compositions of the calixpyrrole macrocycle with solid supports found in the instant specification. This rejection can be overcome by amending the claims to recite "pharmaceutical compositions" and including a pharmaceutically acceptable carrier. This rejection could also be overcome by including specific solid supports attached to the calyx[n]pyrroles.

### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.


The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
\_\_\_\_\_  
Rebecca Anderson  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600  
8/18/05

KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER  
  
for Joseph K. McKane  
Supervisory Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600